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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,645	01/29/2004	Vivekananda M. Vrudhula	CT 2662 DIV1	5570
23914	7590	12/19/2005	EXAMINER	
STEPHEN B. DAVIS			TRUONG, TAMTHOM NGO	
BRISTOL-MYERS SQUIBB COMPANY				
PATENT DEPARTMENT			ART UNIT	PAPER NUMBER
P O BOX 4000			1624	
PRINCETON, NJ 08543-4000			DATE MAILED: 12/19/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/767,645	VRUDHULA ET AL.
	Examiner Tamthom N. Truong	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4-29-04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

This application is a divisional of 10/ 044,183, now U.S. 6,888,004.

Claims 1-6 are pending.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 2, 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process of making compounds of formulae (WHH), (Z') and (AA') wherein R⁸ is -O-C₁₋₄alkyl, or -N(CH₃)(OCH₃), does not reasonably provide enablement for compounds of the process of making compounds of formulae (WHH), (Z') and (AA') wherein R⁸ is *other suitable leaving group*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;

- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims:

Claim 2 recites: “A process for preparing a compound of Formula (WHH)...”;

Claim 4 recites: “A process for preparing a compound of Formula (Z')...”;

Claim 6 recites: “A process for preparing a compound of formula (AA')...”

Although said claims recite specific process, they recite variable R⁸ which represents “—O-C₁₋₄alkyl, or —N(CH₃)(OCH₃) or other suitable leaving group.” The limitation of *other leaving group* includes various moieties and functional groups, and combination thereof. Thus, the scope of claims 2, 4 and 6 is unduly broad.

The amount of direction or guidance presented:

The condition of the processes in claims 2 and 4 uses *high temperature*, and *high-boiling point polar aprotic solvent*, and *suitable silver salt*. Such a condition could displace the *leaving group* represented by R⁸. Likewise, the process of claim 6 uses *phosphoryl trichloride* or *phosphoryl tribromide* which could also displace the *leaving group* represented by R⁸. Thus, the product obtained might not be the one intended. Therefore, the specification does not provide sufficient guidance to make compounds of the above formulae wherein R⁸ is a *leaving group*.

The state of the prior art:

As evident by the teaching of March, when a *leaving group* is a neighboring group, it could change the rate of the reaction of the other leaving group, but it could also be the one affected depending on what the solvent would be (See pages 308-312 of March, ADVANCED ORGANIC CHEMISTRY). Thus, the choice of leaving groups also depends on the choice of solvents and/or other reaction conditions. Therefore, the state of the art prior arts shows the unpredictability of having a *leaving group* as a neighboring group.

The relative skill of those in the art:

Even with the advanced training, the skilled chemist would still have to carry out undue experimentation to make a compound of formulae (WHH), (Z'), and (AA') with R⁸ as a *leaving group* under the condition as recited. Such a task would require a tremendous time, effort, and resource.

The predictability or unpredictability of the art & The quantity of experimentation necessary:

With the unpredictable nature of chemistry, and the limited teaching provided, the skilled chemist would have to carry out undue experimentation to develop of process for making a compound of formulae (WHH), (Z'), and (AA') with R⁸ as a *leaving group*.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

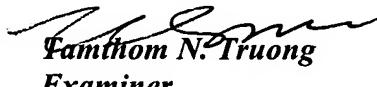
2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. The above claims recite R⁸ as *other leaving group*. Said limitation has indefinite metes and bounds because it is not clear what moieties, functional groups or ring systems is intended. The specification does not define what constitute such a leaving group.
- b. Claims 2 and 4 recite the limitation of a “*high-boiling point polar aprotic solvent*” which has indefinite metes and bounds because the specification does not define what constitute such a solvent. Despite the description of “high-boiling point”, it is still unclear what solvent is intended, especially when R⁸ could be a *leaving group*, and be affected by the choice of solvent.

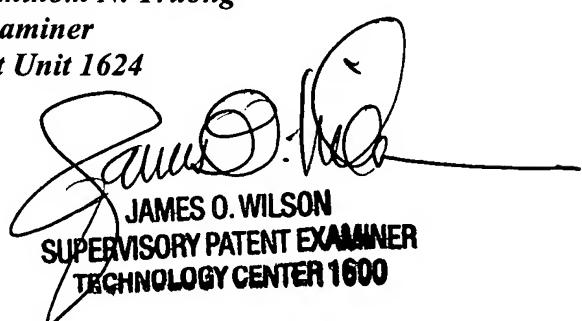
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

12-05-05


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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